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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,892	12/17/2003	Tae H. Ji	50229-424	5602

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,892	JI ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending and under examination.

Priority: The current application was filed December 17, 2003. This application claims priority to provisional application 60/437,729 filed on January 3, 2003. Therefore, the priority date is January 3, 2003.

Specification

The description of the drawings in the specification is objected to because of the following informalities: on page 3, section [12], Fig. 1 should be labeled as Figs. 1A and 1B, and then followed by the correct figure description. This should be applied to the rest of the Figures, as well.

The disclosure is objected to because of the following informalities: on page 5, line 3, the term "Untransfected" should be corrected to "untransfected." Also, throughout the specification, the term "Northern blot" should be corrected to "northern blot." For example, on page 7, end of [25], the capitalized "Northern blot" should be changed to the lower-case "northern blot." In addition, on page 14, section [43], the correct notation for sequence identification numbers is SEQ ID NO: 11, instead of SEQ ID NO. 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 5, 13 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Claims 1-2 and 13 are drawn to a method of modifying the expression of a protein comprising contacting the gene encoding the protein with an effective amount of FSH. FSH is not a transcription factor for any gene, therefore it cannot bind to the gene and turn on expression. Claim 5 is drawn to method for modifying preantral stage and/or early antral stage follicular development wherein follicular development is suppressed. On page 10, line 2 of the instant specification, Applicants disclose "taken together, our results suggest that CTBP mRNA expression in small follicles declines as the follicles develop and grow in response to FSH and hCG, suggesting a complex regulatory mechanism." While it appears that the presence of FSH decreases CTBP mRNA expression, it does not suppress follicular development.

Claims 10-12 rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant claims are drawn to an isolated nucleic acid molecule and an isolated polypeptide, respectively. The claimed subject matter is not supported by a specific and substantial asserted utility. The fact that FSH exposure results in the gene being expressed says nothing about the gene or encoded protein having activity.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 6, 8-9, 13 are drawn to a method of modifying a specific activity as recited in the text of the claims. The use of the term "modify" renders the claims indefinite because it is unclear how the activity will be modified. For example, claim 1 recites, "A method of modifying cytosolic T_3-binding protein (CTBP) gene expression...". It is unclear if modifying cytosolic T_3-binding protein gene expression will increase or decrease the protein gene expression.

Claims 1, 3, 6-9, 13 are drawn to an effective amount of FSH. Neither the claims nor the specification give a clear definition of what constitutes an effective amount.

Claim 2 is indefinite because it is self-dependent. The metes and bounds of the claim cannot be determined.

Claims 4-5 are included in this rejection because they are dependent on claim 1.

Claim 10 is drawn to high stringency conditions. Neither the claim nor the specification defines what high stringency conditions are. Claim 10 is also drawn to an isolated nucleic acid molecule having the nucleotide sequence depicted as SEQ ID NO.12. However, as depicted in the sequence listing provided by Applicant, SEQ ID

NO.12 is a polypeptide sequence, not a polynucleotide sequence. Appropriate correction is required.

Claim 11 is included in this rejection because it is dependent on claim 10.

Claims 12-13 are drawn to a polypeptide of SEQ ID NO.13. However, as depicted in the sequence listing provided by Applicant, SEQ ID NO.13 is a polynucleotide sequence, not a polypeptide sequence. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by McGee et al. (1997 Endocrinology 138(6): 2417-2424). McGee et al. evaluated apoptosis in preantral follicles *in vivo* in rats as well as investigated the effects of activators of the cAMP and cGMP pathways in the regulation of preantral follicle cell apoptosis *in vitro*. McGee et al. teach that treatment with FSH (100 ng/mL) failed to suppress apoptosis in preantral follicles, dissected from ovaries of 12-day-old rats, in culture (p. 2421, Fig. 3; claim 3-4). Because the progression of preantral follicle development is essential to further follicle maturation and ovulation (p. 2417), the effect of FSH on failing to suppress apoptosis in the cultured rat preantral follicles will also

have an effect on ovulation (claim 9). McGee et al. also teach treatment with FSH in combination with either 5% serum or 8-br-cGMP resulted in an increase in the follicular inhibin-α content over that in control follicles, indicating FSH promotes preantral follicle differentiation (p. 2423, Fig. 7; claim 3-4).

Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Adashi et al. (1982 J. Biol. Chem. 257(11): 6077-6083). Adashi et al. teach the effects of estrogens on ovarian aromatase activity *in vitro* using granulosa cells from immature hypophysectomized estrogen-primed rats. The accumulation of estrogen during the test period was used to indicate the level of aromatase activity. Adashi et al. teach the estrogen production by control and diethylstilbestrol (10^{-7} M) – treated cells was negligible, whereas treatment with FSH brought about a substantial increase in aromatase activity (estrogen accumulation: 7.5 +/- 1.0 ng/mg or protein/5 h) (p. 6078, Fig. 1; claim 7-8). Although Adashi et al. do not teach the effect of FSH suppression on CTBP gene expression, this is an inherent property of FSH and meets the limitations of claim 7. Since Adashi et al. teach FSH increases aromatase activity in rat granulosa cells, it must therefore suppress CTBP gene expression.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 13, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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